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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/918,407	08/26/1997	JACK A. ROTH	INGN:050/HYL	6010

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EXAMINER
SANDALS, WILLIAM O

ART UNIT	PAPER NUMBER
1636	41

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
08/918,407	Roth et al.
Examiner	**Art Unit**
William Sandals	1636

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 16, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-10, 12-20, 22-26, 32-37, 39-61, 77-79, 83-91, 96-101, 111, ~~112~~* 112, 116-120, 128-130 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-10, 12-20, 22-26, 32-37, 39-61, 77-79, 83-91, 96-101, 111, 112, ~~113~~* 116-120, 128-130 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Aug 26, 1997* is/are a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 27, 40
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 31, 34,
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Arguments

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

2. Amendments to the claims in Paper No. 39, filed April 16, 2002 have overcome the rejection of the claims under 35 USC 112, second paragraph in the previous office action, and the rejection is withdrawn.

3. Amendments to claim 38 in Paper No. 39 has overcome the objection to the claims in the previous office action, and the rejection is withdrawn.

4. The terminal disclaimers filed in Paper No. 39 have overcome the rejection of the claims under 35 USC 112, first paragraph, obviousness double patenting in the previous office action, and the rejection is withdrawn.

5. Arguments presented in Paper No. 39 have overcome the rejection of the claims under 35 USC 112, first paragraph, enablement, in the previous office action, and the rejection is withdrawn.

6. Arguments and amendments presented in Paper No. 39 have overcome the rejections of the claims under 35 USC 102 in the previous office action, and the rejections are withdrawn.

7. The IDS filed April 24, 2001, Paper No. 27 has been considered and a copy of same is provided with this office action.

Response to Amendment

8. The declarations of Jack Roth and Judith Wilson under 37 CFR 1.132 filed April 16, 2002 are sufficient to overcome the rejection of claims 1-20, 22-26, 46-61, 77-79, 8-91, 96-101, 112-120 and 128-130 based upon 35 USC 112, first paragraph.

Drawings

9. New formal drawings are required in this application because recent changes to the MPEP, section 608.02(c) no longer allow deferral of submission of drawings pursuant to notification. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the Patent and Trademark Office no longer prepares new drawings.

Claim Rejections - 35 USC § 112

10.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-10, 12-20, 22-26, 46-61, 77-79, 83-91, 96-101, 111, 112, 115-120 and 128-130 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 1 recites "a DNA segment encoding a functional p53 protein" at line 2, and at line 4 recites "functional p53 protein". It is not clear if the "functional p53 protein" of line 2 is one

and the same as the "functional p53 protein" of line 4. The language of the claim permits that a "functional p53 protein" may be produced by an exogenous gene in the cell. This raises doubt as to the meaning of the recitation of "functional p53 protein" at line 4 in the claim. Claim 1 is therefore vague and indefinite. It is assumed for the purposes of examination, that the "functional p53 protein" of line 2 encoded by an exogenous DNA segment is one and the same as the "functional p53 protein" of line 4.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuerbitz et al. (of record) in view of Fritsche et al.

The claims are drawn to a composition comprising an exogenous DNA segment encoding a functional p53 polypeptide and a DNA damaging agent. The DNA damaging agent may be any of the compounds described in claim 33 (which are also known as chemotherapeutic compounds - see below).

Kuerbitz et al. taught (see especially materials and methods, figure 4 and the last paragraph) a composition comprising an exogenous DNA segment encoding a functional p53 polypeptide in combination with a DNA damaging agent.

Kuerbitz et al. did not list the DNA damaging agent compounds of claim 33.

Fritsche et al. taught (see especially the introduction) a composition comprising a gene encoding a functional p53 polypeptide in combination with a DNA damaging agent, where the DNA damaging agent may be any of a number of chemotherapeutic compounds as listed in claim 33.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant invention to combine the teachings of Kuerbitz et al. with Fritsche et al. because each of Kuerbitz et al. and Fritsche et al. taught a composition comprising a gene encoding a functional p53 polypeptide in combination with a DNA damaging agent, where Fritsche et al. taught the list of DNA damaging agents which may be any of a number of well known chemotherapeutic compounds as listed in claim 33, and Kuerbitz et al. taught that the "functional p53 protein" may be encoded by an exogenous DNA segment.

One of ordinary skill in the art would have been motivated to combine the teachings of Kuerbitz et al. with Fritsche et al. because Fritsche et al. merely provided the list of the identities of the well known chemotherapeutic agents which were known as DNA damaging agents as described in Kuerbitz et al. Further, a person of ordinary skill in the art would have had a

reasonable expectation of success in the producing the instant claimed invention given the teachings of Kuerbitz et al. with Fritsche et al.

15. Claims 32-37 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuerbitz et al. with Fritsche et al. as applied to claims 32-35 above, and further in view of Bacchetti et al. (of record).

Kuerbitz et al. and Fritsche et al. taught the invention as described above.

Kuerbitz et al. and Fritsche et al. did not teach that the DNA segment encoding p53 was contained in an adenoviral vector.

Bacchetti et al. taught (see especially the abstract, introduction, figures and page 757, last paragraph) the well known use of adenoviral vectors to express a p53 gene.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant invention to combine the teachings of Kuerbitz et al. and Fritsche et al. with the teachings of Bacchetti et al. because Bacchetti et al. taught the well known use of an adenoviral vector for expression of p53 in a cell. It would have been obvious to one of ordinary skill in the art to substitute the well known adenoviral vector of Bacchetti et al. for the plasmid vector of Kuerbitz et al. to provide an expressed p53 gene to the target cell.

One of ordinary skill in the art would have been motivated to combine the teachings of Kuerbitz et al. and Fritsche et al. because Bacchetti et al. taught the advantageous and desirable use of an adenoviral vector which expressed high levels of the gene encoding a p53 polypeptide

in a cell. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Kuerbitz et al. and Fritsche et al. with Bacchetti et al.

16. Claims 32-37 and 39-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuerbitz et al. and Fritsche et al. with Bacchetti et al. as applied to claims 32-37 and 39-41 above, and further in view of the Stratagene Catalogue (of record).

Kuerbitz et al. and Fritsche et al. with Bacchetti et al. taught the invention as described above.

Kuerbitz et al. and Fritsche et al. with Bacchetti et al. did not teach the composition in a kit.

Stratagene catalog teaches "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone

by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the advantageous and desirable use of a composition comprising an expressed gene encoding a p53 polypeptide in a cell in combination with DNA damaging agents which may be used in a method to kill the cells of a tumor with the composition into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches the desirability and advantages for combining reagents of use in an assay into a kit.

One of skill in the art would have been motivated to combine the teachings Kuerbitz et al. and Fritsche et al. with Bacchetti et al. with the teachings of the Stratagene catalogue since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit as recited above. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Kuerbitz et al. and Fritsche et al. with Bacchetti et al. with the Stratagene Catalogue.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Certain papers related to this application are ***welcomed*** to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.
Examiner
June 27, 2002

TERRY MCKELVEY
PRIMARY EXAMINER